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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,469

06/19/2006

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EXAMINER

HAVLIN, ROBERT H

ART UNIT

PAPER NUMBER

1626

NOTIFICATION DATE

DELIVERY MODE

06/03/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com  
PPROCESSING@SUGHRUE.COM  
USPTO@SUGHRUE.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,469	<b>Applicant(s)</b> TANAKA ET AL.	
	<b>Examiner</b> ROBERT HAVLIN	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7,9-13,15,16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,7,9,12,13,15,16 and 81 is/are rejected.
- 7) ☒ Claim(s) 5,10 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

**Status of the claims:** Claims 1, 2, 5, 7, 9-13, 15,16, and 18 are currently pending.

**Priority:** This application is a 371 of PCT/JP04/19456 (12/17/2004) and claims foreign priority to JAPAN P.2003-422431 (12/19/2003) and JAPAN P.2004-101378 (03/30/2004).

### RESPONSE TO APPLICANT REMARKS

#### ***Claim Rejections - 35 USC § 112 - Enablement***

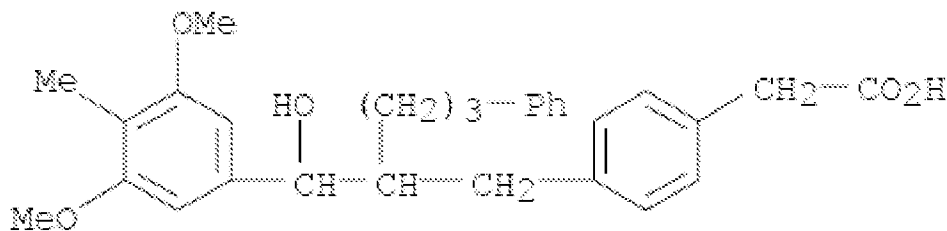
1. Claim 16 was rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for prevention and/or treatment of the claimed disorders with the full scope of compounds encompassed by claim 1.

Applicant has narrowed the scope of claim 1 and persuasively argued how the data presented in the specification and the declarations provide a reasonable correlation between the in vitro measurements and in vivo activity. Accordingly, this rejection is **withdrawn**.

#### ***Claim Rejections - 35 USC § 102***

2. Claims 1, 2, 6, 7, 9, 12, 13, 15, and 16 were rejected under 35 U.S.C. 102(e) as being anticipated by US 2006/0148830.

Example 31 teaches the following compound which anticipates the claims:



Applicant traverses this rejection by claiming that pursuant to MPEP 705.02(f)(1) the publication is not legally effective 102(e) prior art because the International Application was not published in English. The PG PUB has a 102(e) date of 4/4/2005 which is not an effective prior art date. However, the publication is an English language equivalent of the International Application WO/2004/031118 with a publication date of 4/15/2004 which is a proper 102(e) reference.

Nevertheless, this rejection is **withdrawn**.

***Claim Rejections - 35 USC § 112***

3. Claims 1, 2, 5-7, 9, 10, 12, 13, 15, and 18 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds identified as having inhibitory effect with experimental data, does not reasonably provide enablement for the asserted utility of the entirety of the claim scope.

Applicant has narrowed the scope of claim 1 and persuasively argued how the data presented in the specification and the declarations provide a reasonable correlation between the in vitro measurements and in vivo activity. Accordingly, this rejection is **withdrawn**.

4. Claims 1, 2, 5-7, 9-13, 15, 16, and 18 were rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for "solvates thereof." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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Applicant has deleted the objectionable term. Therefore, the rejection is **withdrawn**.

### **NEW CLAIM REJECTIONS**

#### ***Claim Rejections - 35 USC § 102***

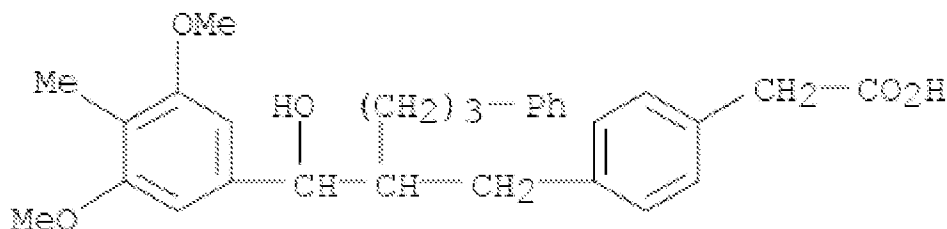
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1, 2, 7, 9, 12, 13, 15, 16, and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by WO/2004/031118. However, the publication US 2006/0148830 is an English language equivalent of the International Application WO/2004/031118 with a publication date of 4/15/2004 which is a proper 102(a) reference.

Example 31 teaches the following compound which anticipates the claims:



7. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

#### ***Claim Objections***

Claims 5, 10, and 11 are objected to for being dependent on a rejected base claim.

***Conclusion***

The claims are not in condition for allowance.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/  
Examiner, Art Unit 1626